IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

A. LUKE SMITH, Plaintiff, v. FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Defendant.	Civil Action No. _____

COMPLAINT

Plaintiff A. Luke Smith, for his complaint against the above-captioned defendant ("Defendant" or "FDA"), alleges as follows:

I. NATURE OF THE ACTION

1. This action is brought pursuant to the Freedom of Information Act ("FOIA" or "the Act"), 5 U.S.C. § 552 (2006), as amended, to compel the production of agency documents and records relating to approval of Abbreviated New Drug Application ("ANDA") numbers 076477, 078773, 091226, 090548, 077575, 091624, 201010, and 202357, improperly withheld from Plaintiff by Defendant Food and Drug Administration ("FDA").

II. JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction over this action under 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331.

3. This Court has personal jurisdiction over Defendant under 5 U.S.C. § 552(a)(4)(B). Defendant maintains a continuous and systematic presence in Pennsylvania,

including a Regional Office located at U.S. Customhouse, Rm. 900, 2nd and Chestnut Streets, Philadelphia, PA 19106.

4. Venue is proper in this District pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391(e) because Plaintiff resides in this District.

III. PARTIES

5. Plaintiff A. Luke Smith submitted various FOIA requests to FDA seeking information about FDA approval of certain generic drugs.

6. Plaintiff works and resides in this district. Plaintiff is a practicing attorney who works at Faruqi & Faruqi, LLP, 101 Greenwood Avenue, Suite 600, Jenkintown, PA 19046. Plaintiff resides at 126 W. Washington Lane, Philadelphia, PA 19144.

7. Defendant FDA is an administration in the Department of Health and Human Services, located at 10903 New Hampshire Avenue, Silver Spring, Maryland, 20993. FDA is charged with responsibility for regulating drugs marketed in the United States. Defendant FDA is an agency within the meaning of 5 U.S.C. § 552(f). Defendant FDA has possession of and control over certain records and documents that Plaintiff seeks.

IV. LEGAL AND FACTUAL BACKGROUND

8. When FDA evaluates an application for approval to market a drug product (e.g., an ANDA), each disciplinary division within FDA produces a "review" of the data submitted by the applicant and FDA's analysis of it. On information and belief, at or around the time an application for approval to market a new drug is approved, FDA compiles these reviews – together with other documents relating to the application including records of correspondence with the applicant and internal briefing regarding the drug product – into what is generally called an "approval package."

9. Once FDA sends a letter approving a drug, the contents of the approval package related to that drug is "immediately available for public disclosure." 21 CFR § 314.430(e) & (f).

10. FOIA provides that "each agency, upon any request for records which . . . reasonably describes such records and . . . is made in accordance with published rules . . . and procedures . . . shall make the records promptly available to any person." 5 U.S.C. § 552(a)(3)(A).

11. Under FOIA, "[e]ach agency, upon any request for records . . . shall . . . determine within 20 days . . . after the receipt of any such request whether to comply with such request and shall immediately notify the person making such request of such determination and the reasons therefor[.]" 5 U.S.C. § 552(a)(6)(A)(i).

12. In accordance with FOIA, FDA regulations state that "[e]xcept where specifically exempt . . . all Food and Drug Administration records shall be made available for public disclosure." 21 C.F.R. § 20.20(b) (2009). "Within 20 working days . . . after a request for records is logged in at the Freedom of Information Staff, the agency shall send a letter to the requester providing the agency's determination as to whether, or the extent to which, the agency will comply with the request, and, if any records are denied, the reasons for the denial." 21 C.F.R. § 20.41(b).

13. When an agency fails to comply with applicable statutory time limits, the requester will be deemed to have exhausted its administrative remedies and may seek relief in federal court. 5 U.S.C. § 552(a)(6)(C)(i) and § 552(a)(4)(B).

14. Once a determination to comply with a FOIA request is made, "the records shall be made promptly available" to the requestor unless the government can show "exceptional

circumstances exist ***and*** that the agency is exercising due diligence in responding to the request[.]" 5 U.S.C. § 552(a)(6)(C)(i) (emphasis added).

15. The term "exceptional circumstances," as expressly limited in the Act, "does ***not*** include a delay that results from a predictable agency workload of requests … unless the agency demonstrates reasonable progress in reducing its backlog of pending requests." 5 U.S.C. § 552(a)(6)(C)(i) (emphasis added).

V. FACTS

A. THE FIRST FOIA REQUEST

16. On November 17, 2011, Plaintiff submitted a "FOIA request for ANDA 76-447 'Approval Package'"[1] ("First FOIA Request") to FDA's Division of Freedom of Information.

17. The First FOIA Request has been outstanding for over twelve (12) months as of the date of this Complaint.

18. On November 21, 2011, FDA acknowledged receipt of Plaintiff's First FOIA Request, stating that FDA would "respond as soon as possible[.]"

19. By email addressed to "druginfo@fda.hhs.gov" dated December 13, 2011, Plaintiff, in part following up on the First FOIA Request, inquired about "the status, and expected availability" of, *inter alia*, the approval package for ANDA 76-447.

20. By email dated December 16, 2011, the Division of Drug Information in the FDA's Center for Drug Evaluation and Research informed Plaintiff that "[t]he information that

[1]The First FOIA Request also sought records related to a citizen petition affecting ANDA 76-447. FDA has produced some widely-available documents responsive to that portion of the request, which is not the subject of this complaint. Additionally, the body of this request referred to the "approval package" in the alternative as "Summary Basis of Approval" or "SBA." However, Plaintiff now understands that this terminology may be outdated or inapplicable, but FDA has construed this request to seek what it reasonably describes, specifically, the "approval package" as that term is described in paragraph eight 8 of this complaint, and in a clarifying footnote in the First FOIA Request, which stated: "It is my understanding that the Approval Package will include all deficiency notices and amendments, … and any applicable FDA Final Reviews."

you requested is covered under the U.S. Freedom of Information Act (FOIA). Such documents are not prepared specifically for public distribution, but are available upon specific written request."

21. In February of 2012, Plaintiff spoke to various representatives at FDA and was told that it would take 18-24 months to process Plaintiff's request for the approval package for ANDA 76-447, but offered to produce it faster if Plaintiff was able to "narrow" its FOIA request, qualifying it for what FDA calls the "simple" queue. Despite the already-narrow request, in light of the delay reported by FDA, Plaintiff attempted to negotiate a narrower request before it became clear that, to qualify for the "simple" queue, the request would have to be too narrow to be useful to Plaintiff.

22. Despite Plaintiff's willingness and flexibility in negotiations to reasonably modify his request, Plaintiff could not convince FDA to spare him an 18-24 month delay, and the parties subsequently abandoned these negotiations.

23. As of the date of this complaint, which is more than twenty working days since FDA received Plaintiff's First FOIA Request, FDA has not responded to Plaintiff's request for the approval package for ANDA 76-447, and has not produced any responsive documents or records.

24. FDA's failure to respond within twenty working days to Plaintiff's First FOIA Request constitutes a violation of the Act and FDA regulations. 5 U.S.C. § 552(a)(6)(A)(i); 21 C.F.R. § 20.41(b).

25. Under § 552(a)(6)(C)(i), Plaintiff has exhausted his administrative remedies with respect to the First FOIA Request because FDA failed to comply with the time limit provisions of 5 U.S.C. § 552(a)(6)(A)(i) for issuing its determination.

26. FDA cannot show that exceptional circumstances exist which justify its projected two-year delay in producing records responsive to Plaintiff's First FOIA Request.

B. THE SECOND FOIA REQUEST

27. On March 14, 2012, without waiver of or prejudice to the First FOIA Request, and without withdrawing or abandoning any portion of the First FOIA Request, Plaintiff submitted a second FOIA request to FDA, limited to certain portions of for the approval package for ANDA 76-447, namely, the Administration and Correspondence section (the "Second FOIA Request"). Plaintiff did so in the hope of obtaining from FDA at least a portion of the approval package for ANDA 76-447 faster than the remainder thereof.

28. The Second FOIA Request has been outstanding for over eight (8) months as of the date of this Complaint.

29. In the Second FOIA Request, Plaintiff stated: "It is my expectation is [sic] that by limiting this request to a single section of the ANDA, it will be treated as a 'simple' request, and thereby avoid the 'complex' request review queue (which I understand can take 18-24 months)."

30. Plaintiff was clear that he was maintaining his First FOIA Request for the full Approval Package in the complex queue.

31. By letter dated March 19, 2012, FDA acknowledged receipt of Plaintiff's Second FOIA Request and stated that FDA "will respond as soon as possible[.]"

32. On July 27, 2012, Plaintiff spoke with an FDA representative, Dashni Patrick, by phone and inquired as to the status of his Second FOIA Request.

33. Ms. Patrick informed Plaintiff that Plaintiff's Second FOIA Request, requesting the Administration and Correspondence section of the approval package for ANDA 76-447, was placed in the "complex" queue behind Plaintiff's First FOIA Request for the full Approval

Package. As a result, Ms. Patrick informed Plaintiff that she was canceling the Second FOIA Request.

34. Plaintiff asked Ms. Patrick to leave the Second FOIA Request open, in case Plaintiff becomes able to narrow the request in the future so as to make the request "simple."

35. Ms. Patrick informed Plaintiff that she would not leave the Second FOIA Request open, and that if Plaintiff became able to narrow his request for the Administration and Correspondence section to a "single letter," he could file a new FOIA request.

36. Ms. Patrick did not state that Plaintiff had a right to appeal this determination, nor did she send Plaintiff a letter stating that his request had been denied and informing him of his right to take an administrative appeal.

37. As of the date of this Complaint, which is more than twenty working days since FDA received Plaintiff's Second FOIA Request, FDA has not responded to the request and has not produced any responsive documents.

38. FDA's failure to respond within twenty working days to Plaintiff's Second FOIA Request constitutes a violation of the Act and FDA regulations. 5 U.S.C. § 552(a)(6)(A)(i); 21 C.F.R. § 20.41(b).

39. Under § 552(a)(6)(C)(i), Plaintiff has exhausted his administrative remedies with respect to the Second FOIA Request because FDA failed to comply with the time limit provisions of 5 U.S.C. § 552(a)(6)(A)(i) for issuing its determination.

40. FDA cannot show that exceptional circumstances exist which justify its projected two-year delay in producing records responsive to Plaintiff's Second FOIA Request.

C. THE THIRD FOIA REQUEST

41. On May 31, 2012, Plaintiff submitted a third FOIA request to FDA for the

approval packages for each of the following ANDA numbers: 078773; 091226; 090548; 077575; 091624; 201010; 202357. Plaintiff refers to the foregoing as the "Third FOIA Request."

42. The Third FOIA Request has been outstanding for over six (6) months as of the date of this Complaint.

43. By letter dated June 4, 2012, FDA acknowledged receipt of Plaintiff's Third FOIA Request, stating that FDA "will respond as soon as possible."

44. As of the date of this Complaint, which is more than twenty working days since FDA received Plaintiff's Third FOIA Request, FDA has not responded to the request and has not produced any responsive documents.

45. FDA's failure to respond within twenty working days to Plaintiff's Third FOIA Request constitutes a violation of the Act and FDA regulations. 5 U.S.C. § 552(a)(6)(A)(i), 21 C.F.R. § 20.41(b).

46. Under § 552(a)(6)(C)(i), Plaintiff has exhausted his administrative remedies with respect to the Third FOIA Request because FDA failed to comply with the time limit provisions of 5 U.S. C. § 552(a)(6)(A)(i) for issuing its determination.

47. FDA cannot show that exceptional circumstances exist which justify its projected two-year delay in producing records responsive to Plaintiff's Third FOIA Request.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this court:

A. Order FDA to promptly produce to Plaintiff the records and documents requested in each of the FOIA requests (First, Second, and Third) pursuant to 5 U.S.C. § 552(a)(4)(B);

B. Enjoin Defendant FDA from withholding the records and documents requested in each of the FOIA requests pursuant to 5 U.S.C. § 552(a)(4)(B);

C. Award Plaintiff costs and reasonable attorney's fees pursuant to 5 U.S.C. § 552(a)(4)(E);

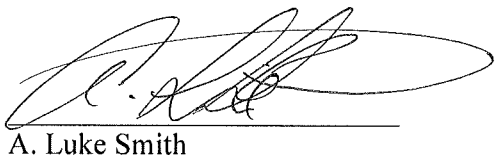
D. Issue a written finding pursuant to 5 U.S.C. § 552(a)(4)(F) that the circumstances surrounding the withholding of documents from Plaintiff raise questions as to whether agency personnel acted arbitrarily or capriciously in exercising their discretion;

E. Enjoin FDA from assessing fees for its delayed responses to these FOIA requests pursuant to 5 U.S.C. § 552(a)(4)(A)(viii);

F. Grant such other relief as the Court deems just.

Dated: December 10, 2012

Respectfully submitted,



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